Supreme Court, U.S.
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No. (1)

In The

Supreme Court of the United States

Mal Son Halliman and Robert W. Halliman
Petitioners

v.

The United States of America
Respondent

On Petition for Writ Of Certiorari to The United States Court of Appeals For the Sixth Circuit.

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Whether the Supreme Court's ruling in *Celotex v. Catrett* justifies an interpretation, in a medical malpractice case, that at the end of discovery merely pointing out that the plaintiff has not produced an expert is sufficient trigger to shift the burden of proof to the plaintiff and prevail in a motion for summary judgment.

Whether summary judgment is appropriate when the movant's motion has not addressed all of the elements of the complaint.

Whether a patient's profound language barrier creates valid issues of fact regarding consent and informed consent .

Whether the court is justified in deciding an issue of fact in order to decide a procedural issue when the issue was not raised in the motion.

LIST OF PARTIES

In addition to the parties shown on the title page the following were parties to the original complaint but have since been dismissed as defendants without objection:

Lt.Col. Darwin Karr-Peterson, United States Army Retired

Blanchfield Army Community Hospital, Ft. Campbell, KY

United States Army

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PETITION FOR WRIT OF CERTIORARI

Petitioner respectfully prays that a writ of certiorari issue to review the judgment below.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Sixth Circuit appears at Appendix A to the petition and is unpublished.

The opinion of the United States District Court, Middle District of Tennessee, Nashville Division appears at Appendix B to the petition and is unpublished.

JURISDICTION

The date on which the United States Court of Appeals for the Sixth Circuit decided our case was December 7, 2007.

No petition for rehearing was timely filed in this case.

An extension of time to file the petition for a writ of certiorari was granted to and including May 5, 2008 on March 19, 2008 in Application No. 07A782.

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Constitutional Provisions Involved:

Article XIV Section 1 of the constitution as quoted below:

> All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

Statutory Provisions Involved

Tennessee Code Annotated § 29-26-115(a)(b) and (c) and TCA § 29-26-118 The statutes are shown in Appendix D:

STATEMENT OF THE CASE

The plaintiffs brought action against the United States, The United States Army, Blanchfield Army Community Hospital and Dr. Darwin Karr-Peterson for negligence in the performance of a colonoscopy during which the colon was punctured, for lack of consent, for lack of informed consent, and poor post-operative care. After a period of discovery, the defense moved for summary judgment on the grounds that the plaintiffs had not secured expert testimony. Plaintiffs responded requesting summary judgment be denied on the grounds that the movant had not met its burden of proof of undisputed fact sufficient to trigger the burden of proof to the plaintiffs, and that the movant had not addressed the issues of consent and informed consent in its motion. Magistrate Judge Bryant concluded that an issue of consent did not exist and that the defense had met its burden of proof consistent with *Celotex v. Cattret,* and recommended summary judgment be awarded to the defense. District Judge Todd Campbell accepted the recommendations of Judge Bryant and granted summary judgment for the defendant, the United States without additional comment. The case against The U.S. Army, Blanchfield Army Community Hospital and Dr. Karr-Peterson remain set for trial inasmuch as no motion to remove them as defendants was ever submitted. The U.S. Attorney has since moved to dismiss these as defendants and the plaintiffs did not oppose.

On April 4, 2007, Magistrate Judge Bryant filed a recommendation to remove the remaining defendants and dismiss the case. On April 23, 2007, District Judge Todd Campbell, filed the Order to

Dismiss the remaining defendants in the case and removed the case from the trial schedule. On April 24, 2007, Plaintiffs filled the Notice of Appeal to the District Court and on June 5, 2007, filled the Appellant Brief with the U.S. Court of Appeals, Sixth Circuit. On December 7, 2007, the U.S. Court of Appeals issued a ruling affirming summary judgment.

Statement of facts relative to issues presented.

The following facts have been stated in the complaint and have not been disputed or challenged by the defense:

1. Plaintiff, Mal Son Halliman is a Korean-born naturalized citizen who does not read or write English whatsoever.

2. Mrs. Halliman has good comprehension of every day basic spoken English but limited comprehension of rapidly spoken English or English language containing technical terminology or complex sentence structure.

3. The consent form that was presented to Mrs. Halliman for signature is written entirely in English and contains many words Mrs. Halliman does not encounter in her normal daily life.

4. Because of her inability to read English, Mrs. Halliman was not able to know and verify the contents of the consent form before signing it.

5. No interpreter was offered or provided to assist Mrs. Halliman in understanding the consent form.

6. Plaintiff's spouse, Robert Halliman was out of town in Louisiana and not present to assist his wife in understanding the consent form or understanding what the doctor was saying.

7. Mrs. Halliman did not want the colonoscopy. She had gone to the surgeon to get a hemorrhoid removed.

8. The doctor, Karr-Peterson, went to great lengths to convince Mrs. Halliman to agree to a colonscopy to the extent of calling Mr. Halliman in Louisiana in order to get Mr. Halliman to convince his wife to agree to the colonoscopy.

9. When Mrs. Halliman finally agreed to the colonoscopy, under pressure, she asked the doctor "who is going to do it?" and he said "I will if you don't mind." Mrs. Halliman did not grant consent to Karr-Peterson but said "I want the best person to do it." These statements were repeated at least two more times during the conversation but were not entered on the consent form.

10. On December 10, 1999, at 06:30am, Mrs. Halliman entered the Same Day Surgery Clinic of Blanchfield Army Community Hospital to have the colonoscopy.

11. In conversation with the intake nurse Mrs. Halliman inquired as to who was going to do the procedure. The intake nurse told Mrs. Halliman that a Dr. Little would be performing the colonoscopy. Mrs. Halliman then stated that she wanted the "best person " to do the procedure.

12. The nurse told Mrs. Halliman that Dr Little was the best person the hospital has because he was a board certified gastroenterologist who does these procedures routinely because of his specialty.

13. Mrs. Halliman, again, said that she wanted the "best person" to do the colonoscopy and the nurse, again affirmed that Dr. Little was the best in BACH for that procedure.

14. Mrs. Halliman was satisfied with the nurse's explanation and settled in to prepare for the procedure that she expected to be done by Dr. Little.

15. Mrs. Halliman was sedated prior to being taken to the procedure room and was not aware that Karr-Peterson was going to do the colonoscopy.

16. Dr. Karr-Peterson performed the colonoscopy during which he tore a hole in the colon necessitating emergency surgery to repair.

17. The instrumentality of the colonoscopy and the resulting puncture was totally in the

control of Dr. Karr-Peterson throughout the procedure.

18. This was Karr-Peterson's second colon puncture during colonoscopy during a six month period and the second puncture in 800 career colonoscopies.

19. Complications from infection during post-operative care required open-wound healing making for a lengthy and difficult recovery period.

REASONS FOR GRANTING THE WRIT

Motions for summary judgment are as commons as lawsuits themselves with FRCP Rule 56 being the foundation for the standard of review. The watershed cases of *Adickes v. Kress* and *Celotex v. Catrett* provided precedence for applying Rule 56, with *Adickes* viewed as having a more restrictive application and *Celotex* looked on as having reversed the restrictive view of Adickes almost eliminating the threshold at which the burden of proof in summary judgment shifts to the nonmovant. There still exists confusion over where that threshold is. Time has caused the threshold to evolve lower and lower to the point where, as in this case, filing a motion without any evidentiary matter automatically triggers the shift of burden of proof to the nonmovant. This is in contravention to the intent of FRCP Rule 56(c) and (e) and the rulings of Courts of Appeal of other Circuits. This case gives the court an opportunity to

realign the standard of review regarding the threshold that shifts the burden of proof to the nonmovant to be more consistent with the intent of Rule 56(c) and (e).

In the present case, the sole basis for the defense motion is that the plaintiff did not have expert testimony at the end of discovery. In other words, rather than present evidence from the record of an absence of disputed material fact, the defense merely said that the plaintiff would not be able to prove its case at trial without an expert. Cited, in support of this position, was the Tennessee statute, TCA § 29-26-115(a) and (b), as well as *Celotex v. Cattret.* The Court of Appeals erroneously upheld this as sufficient grounds to affirm the District Court ruling granting summary judgment to the defendant. The Court's decision is erroneous because it is inconsistent with the language and intent of FRCP Rule 56, inconsistent with the language of *Celotex v. Catrett*, inconsistent with rulings of U.S. Court of Appeals for the Eleventh Circuit, inconsistent with rulings of the U.S. Court of Appeals for the Fifth Circuit, inconsistent with rulings of the Tennessee Supreme Court regarding TCA § 2926-115 (a) and (b) and the requirement for expert testimony in medical malpractice cases, and inconsistent with the ruling of the Tennessee Supreme Court regarding the burden of proof in motions for summary judgment. In fact, the District Court, in the present case, acknowledged that if the burden-of-proof standard set by the Tennessee Supreme Court was applied, the motion for summary judgment would fail. The ruling of the Tennessee Supreme Court regard-

ing the movant's burden-of-proof is consistent with that of the U.S. Court of Appeals for the Eleventh Circuit *Clark v. Coats & Clark, Inc. 929 F. 2d at 608 (C.A. 11(Ga.), 1991),* and the Fifth Circuit. *Russ v. International Paper Co. 943 F. 2d 591 (C.A.5 (Miss.).* The District Court chose to disregard the Tennessee Court's standard on the grounds that it did not apply since this case was in Federal Court and did not consider the rulings of other Federal courts.

The issue of burden of proof

The movant and the court have concluded that showing the lack of expert testimony on the part of the plaintiff was sufficient to show undisputed material fact and warrant summary judgment. Used as the basis for their conclusion was the Supreme Court ruling in *Celotex v. Catrett, 477 U.S. 317, 322-23 (1986),* that has been widely misinterpreted as overruling the courts in *Adickes* by saying the movant does not have to affirmatively negate an essential element of the claim to get summary judgment but can merely assert that the non-movant has no evidence and thereby compel the non-movant to present its evidence *Russ v. International Paper Co. 943 F. 2d 591 (C.A.5 (Miss.). 1991); Clark v. Coats & Clark, Inc., 929 F. 2d 604 (11th Cir. 1991).*

The ruling in *Celotex* did not overrule *Adickes* but rather refined *Adickes* to a more specified set of circumstances. It still requires the movant to make a showing, from the record, sufficient to shift the

burden of proof to the non-movant. What the court really said was that the parties do not have to use affidavits to prove their issues in summary judgment if they can point to other parts of the record to make their case. Judge Cox, of the U.S. Court of Appeals for the Eleventh Circuit, in his very eloquent analysis of *Celotex* in *Clark v. Coats & Clark, Inc. 929 F. 2d at 608(C.A. 11(Ga.), 1991)* stated that

> "Even after Celotex it is never enough simply to state that the non-moving party cannot meet its burden at trial."

The differences in *Celotex*, that are not present in this case, is that in *Celotex*, the plaintiffs asserted that exposure to Celotex products was the source of the health problems of the plaintiff's spouse that led to his death. But, there was nothing in the record that established the facts of the exposure to the products, i.e. how the exposure occurred, the dates, times, places, and duration of exposure, etc. The defense also had presented interrogatories to the plaintiffs requesting the identity of any witness that could testify as to the exposure to Celotex products. The Plaintiffs in *Celotex* could not produce an answer to the interrogatories. Because *Federal Rules of Civil Procedure, Rule 56(c)* provides that citations to the record and answers to interrogatories can be used to show undisputed fact or disputed fact, the fact of a lack of adequate response to interrogatories and the fact that the record showed no facts establishing exposure to Celotex products, the movant was able to point out that the plaintiffs could not prove their case at trial on a fact

material to the case. It was not a "lack of evidence" as in a failure to produce affidavits or expert testimony, but it was a lack of evidence, as in a lack of facts in the record that established the when, where and how of the exposure to Celotex products and the plaintiff was not able to produce any factual evidence to show exposure. The movant in *Celotex v. Catrett* did not merely allege no evidence. It pointed to the absence of evidence of exposure in the record and cited the answer, or lack thereof, to interrogatories, thereby making a "showing" of undisputed material fact sufficient to shift the burden of proof to the plaintiff.

In the instant case the defendant has not submitted any interrogatories to which the Plaintiff should reply. The defense has not pointed to the record and shown that there are no facts in the record supporting the claim. The defense has not established from the record that this case is one that cannot be understood by a layperson without experts. The defense has not declared any witness or expert witness of its own that negates any claim of the Plaintiff. The defense has merely noted that the Plaintiff had not disclosed an expert by the deadline imposed by the court but failed to note that the plaintiffs have provided a witness list and requested documents. Given that the Plaintiffs have provided a witness list and requested documents, it can reasonably be assumed that the Plaintiffs have a strategy for producing testimonial and documentary evidence sufficient to influence a verdict in its favor in one or more of its elements of the complaint. And given that waiving the requirement for expert testimony is a legitimate option for the court, and given

that experts are not required if the facts can be understood by a lay person, it cannot be concluded that the plaintiffs are unable prove their case without experts. Moreover, the defense's failing in submitting interrogatories to the plaintiffs and failure of showing in the record that there is no dispute of material fact, demonstrates that it is unable to negate an essential element of the plaintiff's claim or to show that there is no dispute in material fact. In this it failed to make a "showing" sufficient to trigger the burden of proof to the Plaintiff.

In assessing whether the movant has met this burden, the courts should view the evidence and all factual inferences there from in the light most favorable to the party opposing the motion. *Adickes v. S. H. Kress & Co., 398 U.S. 144, 157, 90 S. Ct. 1598, 1608; Environmental Defense Fund v. Marsh, 651 F.2d 983, 991 (5th Cir. 1981).* All reasonable doubts about the facts should be resolved in favor of the non-movant. *Casey Enterprises v. Am. Hardware Mutual Ins. Co., 655 F.2d 598, 602 (5th Cir. 1981).* If the record presents factual issues, the court must not decide them; it must deny the motion and proceed to trial. *Environmental Defense Fund v. Marsh, 651 F.2d 983, 991 (5th Cir. 1981); Lighting Fixture & Elec. Supply Co. v. Continental Ins. Co., 420 F.2d 1211, 1213 (5th Cir. 1969).* Summary judgment may be inappropriate even where the parties agree on the basic facts, but disagree about the inferences that should be drawn from these facts. *Lighting Fixture & Elec. Supply Co. v. Continental Ins. Co., 420 F.2d at 1213.* If reasonable minds might differ on the inferences arising from undisputed facts, then the court should deny summary judgment. *Impossible Elec-*

tronic Techniques, Inc. v. Wackenhut Protective Systems, Inc., 669 F.2d at 1031; Croley v. Matson Navigation Co., 434 F.2d 73, 75 (5th Cir. 1970); Environmental Defense Fund v. Marsh, 651 F.2d 983, 991 (5th Cir. 1981); United States Steel Corp. v. Darby, 516 F.2d 961, 963 (5th Cir. 1975). The District Court and the U.S. Court of Appeals have not properly applied these standards of review. They did not view the evidence and factual inferences in the light most favorable to the nonmovant. They did not resolve reasonable doubts about the facts in favor of the nonmovant. And, they did not resolve differences of opinion on the implications of undisputed fact in favor of the nonmovant.

Celotex v. Catrett interpreted FRCP Rule 56 (c) and (e) quite correctly as not requiring the use of affidavits as evidence in making a "showing". However, the Advisory Committee notes to the 1963 amendment which added paragraph (e) was quite clear regarding the intent of Rule 56(c) and (e) and the burden of proof for the movant in summary judgment. In the last paragraph of the Advisory Committee notes it states

> **"where the evidentiary matter in support of the motion does not establish the absence of a genuine issue, summary judgment must be denied even if no opposing evidence matter is presented."**

Celotex upheld this standard because the defense was able to show from the record an absence

of facts material to the case. In the instant case, the defense has not presented any evidence of undisputed material fact that would shift the burden of proof to the non-movant.

The issue of expert testimony

The movant and the court have concluded that the absence of expert testimony at the end of discovery means that the plaintiff is unable to prove its case on an issue of material fact. Both cite *Tennessee Code Annotated § 29-26-115(b)* as requiring expert testimony in cases of medical malpractice. However, the requirement for expert testimony under *TCA § 29-26-115(b)* is not absolute. There are at least three other provisions in Tennessee law that will allow a malpractice case to move forward without experts. First, in the last sentence of *TCA § 29-26-115(b)*, it states that the court may waive the requirement for expert testimony when it is apparent that experts will not be available. There is no other language in the statute that would restrict the application of this provision. This provision legitimately allows the case to proceed with whatever evidence the parties can muster through witness and documentary evidence. The Magistrate Judge totally ignored this provision in the statute, as did the District Judge and the CA judges. Second, the law also provides that, in the absence of experts, the plaintiffs may be able to use a *res ipsa loquitur* approach.*Seavers v Oak Ridge Methodist Med. Ctr., 9 S.W.3d 86 (Tenn., 1999)*. Third, Tennessee courts have also ruled that malpractice cases can proceed without experts when the facts

material to the case can be understood and weighed by the lay person who would be the trier of fact *Seavers v Oak Ridge Methodist Med. Ctr., 9 S.W.3d 86 (Tenn., 1999);Bowman v. Henard, 547 S.W. 2d 527(Tenn.1977);Baldwin v. Knight, 569 S.W. 2d 450 (Tenn.1978).* Tennessee courts have also ruled that a theory of medical battery based on lack of consent does not require expert testimony because the question is simply one of did he or she consent or not.

Given these provisions in the code and case law, and given that the courts should view the evidence and all factual inferences there from in the light most favorable to the party opposing the motion, *Adickes v. S. H. Kress & Co., 398 U.S. 144, 157, 90 S. Ct. 1598, 1608; Environmental Defense Fund v. Marsh, 651 F.2d 983, 991 (5th Cir. 1981),* and given that the movant has not made a showing that the alleged malpractice, lack of informed consent and lack of consent are beyond the ability of the layperson to understand, it is therefore an error for the court to conclude that the non-movant cannot prove its case without an expert.

Summary judgment may be inappropriate even where the parties agree on the basic facts, but disagree about the inferences that should be drawn from these facts. *Lighting Fixture & Elec. Supply Co. v. Continental Ins. Co., 420 F.2d at 1213.* If reasonable minds might differ on the inferences arising from undisputed facts, then the court should deny summary judgment. *Impossible Electronic Techniques, Inc. v. Wackenhut Protective Systems, Inc., 669 F.2d at 1031 (C.A.5 (Fla.), 1982); Croley v. Mat-*

son Navigation Co., 434 F.2d 73, 75 (5th Cir. 1970); Environmental Defense Fund v. Marsh, 651 F.2d 983, 991 (5th Cir. 1981); United States Steel Corp. v. Darby, 516 F.2d 961, 963 (5th Cir. 1975).

In the instant case, that the plaintiffs had no expert at the end of discovery can lead to a number of widely differing and opposing conclusions. The defense conclusion is that the plaintiff would be unable to prove its case at trial. Another conclusion is that, given the time remaining until trial, it is possible that an expert could be forthcoming in that time. Another possible conclusion is that the plaintiffs could prove their case with a preponderance of evidence and a *res ipsa loquitur* approach. Another possible conclusion is that the plaintiffs could prove their case on factual issues within the common experience and knowledge of the layperson without the aid of experts using documentary and witness testimony. Because these are all within the realm of possibility, the defense's presumption, that its conclusion is the only conclusion that can be made from the facts, is faulty and therefore renders summary judgment inappropriate.

This is not unlike the court's ruling in *Adickes v. S. H. Kress & Co., 398 U.S. 144, 157, 90 S.Ct. 1598, 1608, (1970).* In *Adickes*, the plaintiff claimed that management or other employees in S.H. Kress had violated her civil rights by colluding with a police officer to drum up a reason to evict the plaintiff from the premises and have her arrested. Kress moved for summary judgment by saying there was no evidence of any collusion and supported it with some evidence that that management had not spoken

to a policeman and testimony from some that they did not see a policeman in the store. The district court granted summary judgment on these grounds and the court of appeals affirmed. The Supreme Court, however, reversed because Kress had not "foreclosed the possibility" of a policeman being in the store. In the instant case, the movant has not foreclosed the possibility of the plaintiff being able to prove its case without experts.

The plaintiffs have also presented an issue of simple consent. Expert testimony is not required for cases involving simple consent. *Blanchard v. Kellum, 975 S.W.2d 522, 524 (Tenn. 1998).* The issue of consent is clearly brought out in the complaint in paragraph 4, bullet 4. and the "background" paragraph of the attachment to the administrative claim, which was signed under penalty of perjury. Although the magistrate judge concluded that simple consent did not exist in the complaint, the fact of the plaintiff's inability to read and write English, the fact that the consent form was written in English, the fact of the plaintiff's limited comprehension of spoken English, the fact of usage of technical terms and complex sentences by Dr. Karr-Peterson, and the fact that the plaintiff said several times that she wanted the "best" person to do the procedure, could cause a reasonable person to conclude that an issue of simple consent exists. Again, If reasonable minds might differ on the inferences arising from undisputed facts, then the court should deny summary judgment. *Croley v. Matson Navigation Co., 434 F.2d 73, 75 (5th Cir. 1970); Environmental Defense Fund v. Marsh, 651 F.2d 983, 991 (5th Cir. 1981); United*

States Steel Corp. v. Darby, 516 F.2d 961, 963 (5th Cir. 1975)

The importance of language precision

Words mean things. A wrong word or an improperly used word can drastically change the meaning of a statute or ruling. For this reason legislators are quite careful in crafting the language used in the statutes they pass. Judges, likewise, are careful to craft the language used in their opinions, because they know that the opinion may be used as precedent in subsequent cases of similar nature. This is an opportunity for the Court to clarify the role and importance of the language used in a statute or court ruling in determining the meaning or intent of the statute or ruling.

In the present case, the Court of Appeals erred by making an interpretation and ruling on a Tennessee Supreme Court case that was inconsistent with the language used. The petitioner cited Blanchard v. Kellum as support for their consent claim and that simple consent cases do not require expert testimony. The Tennessee Supreme Court, in Blanchard v. Kellum presented a simple, two-question test to determine if a case was a medical battery theory based on a lack of simple consent, or one of informed consent. The relevant portion of the court's ruling is quoted below:

> We believe that there is a distinction between: (1) cases in which a doctor performs an unauthorized procedure; and (2) cases in which the procedure is au-

thorized but the patient claims that the doctor failed to inform the patient of any or all the risks inherent in the procedure. Performance of an unauthorized procedure constitutes a medical battery.

A simple inquiry can be used to determine whether a case constitutes a medical battery: (1) was the patient aware that the doctor was going to perform the procedure (i.e., did the patient know that the dentist was going to perform a root canal on a specified tooth or that the doctor was going to perform surgery on the specified knee?); and, if so (2) did the patient authorize performance of the procedure? A plaintiff's cause of action may be classified as a medical battery only when answers to either of the above questions are in the negative. If, however, answers to the above questions are affirmative and if the plaintiff is alleging that the doctor failed to inform of any or all risks or aspects associated with a procedure, the patient's cause of action rests on an informed consent theory.

Both, the District Court and the Court of Appeals interpret the language of *Blanchard v. Kellum* in test number one as referring only to the procedure and does not address the knowledge of the spe-

cific practitioner. Petitioners disagree with this interpretation. In law, language takes on great importance because of what is riding on the meaning of the language. The language structure is important here. In test one, the use of the definite article "the" is important. The definite article denotes specificity. If knowledge of a particular doctor was not intended in the meaning of the test then the indefinite article "a" would have been more appropriate with the read as "was the patient aware that a doctor would perform the procedure?" Or, no reference to doctor would have been made such as, "Was the patient aware that the procedure was going to be done?" However, the fact is that the test does use the term "the doctor" with all the specificity it implies.

If knowledge of the specific doctor was not the intent of the language of test one, then the remaining part of test one makes no sense in view of test two because an affirmative answer to test two automatically make the answer to test one affirmative. A negative answer to test two would make no sense if test one was affirmative, because why would someone not consent and then go into a hospital and subject themselves to the procedure?. It would not make sense for one to say that she did not know the procedure was going to be performed (test one) and then say she consented to it (test two.) However, a reading of the two tests as including specific knowledge of who the practitioner performing the procedure would be would allow differing answers to both tests and still retain logic. That test one is really focusing on the specific practitioner makes test two more sensible. One could then say in test two that consent was given to the procedure but in test one

say that consent was not given to that practitioner. Or, in test one, one could say "I knew the procedure was going to be done, but I did not know that doctor was going to do it." And in test two say, I consented to the procedure but did not consent to that doctor.

Factual issues v. procedural issues

Sometimes factual issues are so closely intertwined with procedural issues that deciding a procedural issue in summary judgment means deciding issues of fact. Since the standard of review is that judges should not decide issues of fact in summary judgment proceedings, what is the standard of review regarding the procedural issue v. the factual issue when they are so closely intertwined? This is an opportunity for the court to establish a standard of review regarding whether it is appropriate to decide a factual issue in order to move on a procedural issue.

The present case is one of those where the procedural intertwines with the factual. The plaintiffs pointed out that they had raised the issue of consent in the complaint and that the issue was not addressed in the motion for summary judgment. The procedural question is simply did the plaintiffs raise the consent issue in the complaint? and if so, did the movant address the issue in the motion? The factual issue is whether or not the plaintiff consented to the colonoscopy. A California Court of Appeals clearly stated that the adequacy of a written consent is a factual issue for a jury *Quintanilla v. Dunkelman. B171789 at 24(CA 9/12/2005)(CA,*

2005). In the present case, when the U.S. Court of Appeals ruled that the patient had consented to the procedure, it was deciding a factual issue in contravention to the standard of review. It erroneously decided the factual issue in order to make the ruling under the test of *Blanchard v. Kellum* that the plaintiff's case was informed consent rather than simple consent.

The issue of simple consent is stressed here for several reasons. One, it was brought out in the complaint. Two, it is an issue that does not require expert testimony under Tennessee Law. Three, it was not addressed in the motion for summary judgment. And four, the standard of review is that all of the essential elements of the complaint must be addressed in the motion for summary judgment or the motion will fail. Therefore, even if the nonmovant did not prevail on the other issues in the motion, the motion should have failed on this issue alone.

The role of Language Barriers in consent and informed consent

In a nation of a rapidly increasing immigrant population, language barriers are an ever present factor in relationships. This case is an opportunity to establish guidelines for determining the relevance of language barriers in issues of consent and informed consent and other issues where language barriers can have a profound effect. The importance of this issue at the national level is that often, citizens with language barriers are not afforded equal

protection under the law that our constitution guarantees.

For example, under Tennessee law a written consent presumes the person signing the consent has read and understood what he or she is signing. This is shown in the following quote from *Church v Perales, 39 S.W.3d 149 (Tenn. Ct. App., 2000)*

> As a general matter, the law presumes that persons who sign documents, having been given an opportunity to read them, are bound by their signatures. *Solomon v. First Tenn. Bank, 774 S.W.2d 935, 943 (Tenn. Ct. App. 1989).* This rule applies in medical battery and informed consent cases. Thus, the law presumes that patients ordinarily read and take whatever other measures are necessary to understand the nature, terms, and general meaning of consent forms involving medical treatment. *Karp v. Cooley, 349 F. Supp. 827, 835 (S.D. Tex. 1972); Grannum v. Berard, 422 P.2d 812, 815 (Wash. 1967).* This presumption has been codified in many states. See, e.g., *Parikh v. Cunningham, 493 So. 2d 999, 1001 (Fla. 1986); Cardio TVP Surgical Assocs. v. Gillis, 528 S.E.2d 785, 787 (Ga. 2000); Shahinaw v. Brown, 963 P.2d 1184, 1188 (Idaho 1998); Earl v. Ratliff, 998 S.W.2d 882, 891 (Tex. 1999).* Thus, the existence of a signed consent form gives rise to a presumption of consent in the absence of

proof of misrepresentation, inadequate disclosure, forgery, or lack of capacity.

Amendment XIV of the constitution guarantees citizens equal protection under the law. It is not an accurate or fair presumption to presume all of our naturalized citizens are able to read and write English or comprehend complex spoken language. The fact is that many are not. The statutes and law that presumes that persons, whose native language is not English, can read and understand that which is presented in English for signature, put these citizens at a disadvantage. Therefore, they are not being given the equal protection of the law.

The last sentence in the case law quoted above suggests that evidence of lack of capacity could annul a signed consent form. The concept of language barrier goes right to the issue of capacity. Capacity is defined as the ability to understand (Terry, Peter B, M.D. Informed Consent in Clinical Medicine, *Chest Journal, 131:563-568,* American College of Chest Physicians, 2007.)(Appendix D). When a patient has a language barrier sufficient to limit his or her understanding of what the practitioner is saying, and when the language barrier is such that the patient cannot read and understand what is written on a consent form he or she is asked to sign verifying that he or she has been informed, the capacity to consent or provide informed consent is severely limited rendering the consent

questionable at best. Such is the situation in the present case. The plaintiff brought out the issue of language barrier in the complaint, and addressed it in their response to the motion for summary judgment and in the brief to the appellate court. Yet, both the District Court and the U.S. Court of Appeals chose to ignore the roll of language barrier in the issues of consent and informed consent.

On the issue of informed consent, the normal burden of proof on the plaintiff at trial is to prove by expert testimony that the practitioner did not supply the appropriate information according to the standard of acceptable practice for that specialty and that medical community. TCA § 29-26-118. Again, the statute ignores the role of language barrier in capacity. If the case for lack of informed consent can be prosecuted on grounds of lack of capacity due to a language barrier, the need for expert testimony would not be necessary because the concept of language barriers are within the common knowledge of laypersons who would be triers of fact. *Seavers v Oak Ridge Methodist Med. Ctr., 9 S.W.3d 86 (Tenn., 1999).*

The issue of verbal conditions to consent

The final question the petitioners ask the court to review is whether verbal conditions to consent nullify consent if not met. In the present case it is fact that the plaintiff

told Dr. Karr-Peterson at least three times that she wanted the best person to do the colonoscopy. She verbalized this at least three more times to the intake nurse on the morning of the procedure. Petitioners have contended that Karr-Peterson did not have consent to perform the colonoscopy because he was not the best person, given an experienced, board-certified, gastroenterologist was available. This issue was brought out in the complaint but not addressed in the motion for summary judgment. It was brought out again in the plaintiff's response to the motion, their response to the recommendations of the magistrate judge, and in the brief to the appellate court. Neither the District Court or the U.S. Court of appeals addressed this issue. The only comment the defense has made is that it would require expert testimony to determine who the best person was. Plaintiff's disagree because comparing experience and qualifications and history of complications resulting from procedures is well within the ability of the lay person to understand. Petitioners have found no case law addressing the issue but feel it important, not only in this case but in cases of others similarly situated.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Mal Son Halliman,
1764 Heritage Drive
Clarksville, TN 37043
(931) 624-1378

And

Robert W. Halliman
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Pro Se

APPENDIX A

No. 07-5509

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Filed Dec 7, 2007

Mal Son Halliman, Robert W. Halliman	)	
Plaintiffs-Appellants	)	On appeal from the United States District Court for the Middle District of Tennessee
v.	)	
UNITED STATES Of AMERICA	)	
Defendant-Appellee	)	
United States Army; Blanchfield Army Community Hospital; Darwin D. Karr-Peterson, LTC. Ret.	)	
Defendants	)	

ORDER

Before: BOGGS, Chief Judge; GIBBONS, Circuit Judge; BELL, Chief District Judge.

Mal Son Halliman and Robert W. Halliman, wife and husband, appeal pro se the summary judgment for the United States in a case filed under the Federal Tort Claims Act (FTCA), 28 U.S.C. § 1346(b)(1). This case has been referred to a panel of the court pursuant to Rule 34(j)(1), Rules of the Sixth Circuit. Upon examination, this panel unanimously agrees that oral argument is not needed. Fed.R.App.P. 34(a).

The Hallimans filed a complaint against an army surgeon, a hospital, the Army, and the United States, alleging that the surgeon committed malpractice when Mal Son Halliman's colon was punctured during a colonoscopy and that her follow-up care was also deficient. Mal Son Halliman pointed out that she is not a native English-speaker and that she believed the colonoscopy was going to be performed by a different doctor. Her administrative claim had been denied due to her failure to produce a medical expert to support her claim.

The defendant United States moved for summary judgment on the sole ground that the Hallimans had not submitted any expert testimony to support their claim. A magistrate judge recommended that the motion be granted. Over the Hallimans" objections, the district court adopted the magistrate judge's recommendations and granted summary judgment to the United States; the remaining defendants were dismissed in a separate final judgment order.

On appeal, the Hallimans challenge only the summary judgment for the United States, reasserting the arguments they raised below.

Upon de novo review, we conclude that the summary judgment for the United States must be affirmed because there is no genuine issue of material fact and defendant is entitled to judgment as a matter of law. *LaPointe v. United Autoworkers Local 600,* § F.3d 376, 378 (6th Cir. 1993).

Under Tennessee law, expert witnesses are required to support acclaim of malpractice. Tenn.Code Ann. § 29-26-115. Defendant pointed out in its motion for summary judgment that the Hallimans had produced no expert witnesses and therefore could not establish an essential element of their case on which they bore the burden of proof. *Celotex Corp. v. Catrett,* 477 U.S. 317, 322-23 (1986). The Hallimans argue that defendants are required to do more than point to an absence of evidence to support a plaintiff's case to successfully move for summary judgment under Tennessee Law. However, federal rules of procedure apply in federal district courts. *Gafford v. General Elec. Co.,* 997 F.2d 150, 165-66 (6th Cir. 1993).

The Hallimans also argue that there are exceptions to the requirement of supporting a malpractice complaint with expert testimony. They cite *Seavers v. Methodist Med. Ctr. Of Oak Ridge,* 9 S.W. 3d 86 (Tenn. 1999), for the proposition that expert testimony may not be necessary to prove negligence. The court in *Seavers* did hold that the doctrine of res ipsa loquitur could raise an inference of negligence

but also noted that expert testimony was necessary to prove other elements of a malpractice case, such as the standard of care. *Id.* at 96. The Hallimans also argue that expert testimony is not necessary in claims of informed consent or medical battery, citing *Blanchard v. Kellum,* 975 S.W. 3d 522 (Tenn. 1998). *Blanchard,* however, expressly states that expert testimony is required for informed consent claims *Id at 524.* Although it provides that expert testimony is not necessary for medical battery claims,, it also defines such claims as involving patients who did not know of or authorize a medical procedure. *Id.* In this case, the evidence showed that Mal Son Halliman knew she would be undergoing a colonsoscopy and had authorized its performance. The Hallimans attempt to add a requirement that she had to know which doctor would be performing the procedure, but a reading of *Blanchard* does not support the existence of such a requirement.

Accordingly, the summary judgment for the United States is affirmed for the reason stated by the magistrate judge and adopted by the district court. Rule 34(j)(2)©, Rules of the Sixth Circuit.

ENTERED BY ORDER OF THE COURT

Leonard Green, Clerk

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

FILED 2-27-2007

Mal Son Halliman, et.al.	)	
	)	No. 3:06-0037
v.	)	JUDGE CAMPBELL
	)	
UNITED STATES	)	
OF AMERICA, et.al.	)	
	)	

ORDER

Pending before the court are a Report and Recommendation of the Magistrate Judge (docket No. 26) and the Plaintiff's objections thereto (Docket Nos. 29 and 30). The court has reviewed the Report and Recommendations, Plaintiffs' Objections, and the file. Plaintiffs' Objections are overruled and the Report and Recommendation is adopted and approved.

Accordingly, the Motion for Summary Judgment filed by Defendant United States (Docket No. 20) is GRANTED, and Plaintiffs' claims against the United States are DISMISSED.

Three named Defendants remain in this actions (United Stated Army, Blanchfield Army Community Hospital, and Darwin D. Karr-Peterson). Al-

though Defendant United States has denied that these three are appropriate Defendants (Docket No. 15 ¶ 3), No Order has been sought or entered dismissing them.

Accordingly, this matter remains set for trial on May 29, 2007, with a pretrial conference on May 14, 2007.

IT IS SO ORDERED

TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE

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APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

FILED 2-15-2007

Mal Son Halliman, et.al.	)	
Plaintiffs	)	No. 3:06-0037
v.	)	Judge Campbell/Bryant
	)	
UNITED STATES OF	)	
AMERICA, et.al.	)	
Defendants	)	

To: The Honorable Todd J Campbell

REPORT AND RECOMMENDATION

The District Judge referred this case to the Magistrate Judge pursuant to 28 U.S.C. § 636 and 72, Federal Rules of Civil Procedure, for a report and recommendation on ay dispositive motions (Docket entry No. 3). Magistrate Judge Brown thereafter transferred this case to the undersigned (Docket Entry No. 19).

Pending before the court is defendant's motion for summary judgment, premised upon the plaintiffs' lack of an expert witness (Docket Entry No. 20).

For the reasons stated below, the undersigned RECOMMENDS that defendant's motion for summary judgment be GRANTED and that the complaint be DISMISSED.

The Complaint

Plaintiffs Mal Son Halliman and husband, Robert W. Halliman, proceeding pro se, have filed this medical malpractice action pursuant to the Federal Tort Claims Act, 28 U.S.C. § 1346 (b)(1), seeking to recover damages allegedly sustained by plaintiffs as the result of a negligently performed colonoscopy on Mrs. Halliman at Blanchfield Army Community Hospital on September 10, 1999. The complaint alleges (1) that the Army surgeon who performed the colonoscopy breached the standard of care by using excessive force that caused a perforation; (2) that the surgeon was negligent in his follow-up care of Mrs. Halliman; (3) that that the surgeon failed to obtain Mrs. Halliman's informed consent by failing to inform her adequately of the risks of the procedure, in view of her inability to read and write English, before securing her signature on the surgical consent form; and (4) that the staff of Blanchfield Army Hospital breached the standard of care by their poor postoperative care of Mrs. Halliman.

Defendant's Summary Judgment Motion

By order of the court, plaintiffs were to serve their Rule 26(a)(2)(B) expert witness reports on or

before August 31, 2006 (Docket Entry No. 17). This deadline has expired and plaintiffs have served no expert witness reports. Defendant has filed its motion for summary judgment pursuant to Rule 56, Federal Rules of Civil Procedure, premised on the sole ground that "plaintiff has not obtained or retained an expert medical witness to support the allegations in her complaint and who has agreed to testify in this case." (Docket Entry No. 22). Defendant argues that, without an expert witness, plaintiffs as a matter of law are unable to establish a genuine issue of material fact for trial. Plaintiffs, in response, maintain (1) that merely asserting plaintiffs' lack of proof is insufficient to support a motion for summary judgment, and (2) that the complaint includes a claim of medical battery, which does not require expert testimony (Docket Entry No. 24).

Analysis

In actions brought under the Federal Tort Claims Act, the Court is required to apply the law of the place where the alleged negligent act or omission of the government occurred. Richards v. United States, 3 U.S. 1, 9-10 (1962); Lloyd v. Cessna Aircraft Co., 434 F. Supp. 4, 5 (E.D. Tenn. 1976). Accordingly, the law of Tennessee applies to this medical malpractice claim against the government.

Tennessee Code Annotated section 29-26-115(a) lists the elements of a medical malpractice claim under Tennessee law, as follows:

> In a malpractice action, the claimant shall have the burden of proving by evidence as provided by subsection (b); (1) The recognized standard of acceptable professional practice in the profession and the specialty thereof, if any, that the defendant practices in the community in which or in a similar community at the time the alleged injury or wrongful action occurred.
>
> (2) that the defendant acted with less than or failed to act with ordinary and reasonable care in accordance with such standard; and
>
> (3) As a proximate result of the defendant's negligent act or omission, the plaintiff suffered injuries which would not otherwise have occurred.

Subsection (b) of this provision states that no person shall be competent to testify as an expert to establish the elements in subsection (a) unless the person was licensed and practicing in Tennessee or a contiguous bordering state during the year before the alleged injury or wrongful act occurred. Tenn.Code Ann. § 29-26-115 (b).

In Tennessee, negligence and causation in medical malpractice cases are ordinarily required to be proved by expert medical testimony. Stokes v. Leung, 651 S.W. 2d 704, 706 (Tenn. Ct.App. 1982).

Rule 56 (c) of the Federal Rules of Civil Procedure, describing summary judgment, states in pertinent part as follows:

> The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admission on file, together with affidavits, if any, show that thee is no genuine issue of any material fact and that the moving party is entitled to judgment as a matter of law.

(emphasis added). Here, the defendant seeks to establish that there is "no genuine issue of any material fact" for trial by asserting (1) that plaintiffs have not obtained a medical expert witness to testify at trial, and (2) that under Tennessee law expert testimony is required to prove the elements of a medical malpractice case. Plaintiffs, in response, apparently concede that they have no medical expert, but they argue (1) that under Tennessee law merely asserting the plaintiffs' lack of proof is insufficient to support a motion for summary judgment, and (2) that their complaint includes a claim for medical battery that does not require expert witness testimony.

The first issue present here is whether a defendant must negate an essential element of the plaintiffs' case in order to sustain a motion for summary judgment, or whether, instead, merely asserting the plaintiffs' lack of evidence is sufficient. On this issue Tennessee and federal law differ. Tennes-

see courts have held that merely asserting a plaintiff's lack of evidence is insufficient to support a motion for summary judgment. See McCarley v. West Quality Food Services, Inc., 960 S.W. 2d 585, 589 (Tenn. 1998); Byrd v. Hall, 847 S.W. 2d 208, 214 (Tenn. 1993). Speaking to this issue, the Tennessee Supreme Court has stated:

> A party seeking summary judgment must demonstrate the absence of any genuine and material factual issues. Byrd v. Hall, 847 S.W. 2d 208, 214 (Tenn. 1993). Mere "conclusory assertion (s) that the non-moving party has no evidence is clearly insufficient." Id. At 215. The movant must either affirmatively negate an essential element of the non-movant's claim or conclusively establish an affirmative defense. Id.at 215 n. 5. If the movant does not negate a claimed basis for the suit, the non-movant's burden to produce either supporting affidavits or discovery materials is not triggered and the motion for summary judgment fails. Id.

McCarley, 960 S.W. 2d at 588. Thus, under Tennessee law, the government's assertion that plaintiffs are without expert witness testimony would be insufficient to support a motion for summary judgment.

In contrast, the U.S. Supreme Court has held that it is not necessary to negate an essential element of the plaintiff's case. The Court stated as follows:

> In our view, the plain language of rule 56 (c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be "no genuine issue as to any material fact," since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial.
>
> . . .
>
> But unlike the Court of Appeals, we find not express or implied requirement in Rule 56 that the moving party support its motion with affidavits or other similar materials negating the opponent's claim. On the contrary, Rule 56 (c), which refers to "the affidavits, if any" (emphasis added), suggest the absence of such a requirement.

Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986) (emphasis in original). Accordingly, if federal law governs, the government is not required to negate an element of plaintiffs' case, and a suggestion of plaintiffs' lack of expert testimony is sufficient.

Although the substantive medical malpractice law of Tennessee governs this case, Richards v. United States, 369 U.S. at 9-10, Rule 56 of the Federal Rules of Civil Procedure has been held to control summary judgment practice in district court, unaffected by state procedural rules. Schultz v. Newsweek, Inc. 668 F. 2d 911, 917 (6th Cir. 1982). The Court of Appeals for the Sixth Circuit has stated:

> Gafford next contends that the district court erred in applying Rule 56 of the Federal Rules of Civil Procedure instead of the Kentucky summary judgment standard in disposing of GE's motion for summary judgment. She essentially argues that, since Kentucky's procedural rules and case law relating to summary judgment affect substantive legal rights, a federal court in diversity should apply Kentucky's summary judgment standard as expressed in Steelvest, Inc. v. Scansteel Serv. Ctr., Inc. 807 S.W. 2d 476 (Ky. 1991). Gafford's argument is readily put to rest. This court rejected such an argument in Reid v. Sears, Roebuck & Co., 790 F. 2d. 453, 459 (6th Cir. 1986). In

that case, employees asserted claims of wrongful discharge in a Michigan state court. The claims were removed to federal court on the basis of diversity of citizenship. The district court granted summary judgment in favor of the employer, and the employees appealed. The employees argued, inter alia, that the court erred in applying the standards of Rule 56 of the Federal Rules of Civil Procedure to the case. This court expressly rejected that argument;

> "(One of the employees contends that) Sears would not have qualified for summary judgment under Michigan law and that the outcome of a diversity case should not be different in a federal court than it would have been in the state whose substantive law controls. This argument fails to recognize the difference between procedural rules and substantive laws. The Federal Rules of Civil Procedure are the rules of practice which apply to civil actions in the federal courts, regardless of whether jurisdiction is based federal question or diversity of citizenship."

Gafford v. General Electric Co., 997 F.2d 150, 165-66 (6th Cir. 193) (quoting Reid v. Sears, Roebuck & Co., 790 F.2d 453, 459 (6th Cir. 1986). Thus, federal procedural law controls the disposition of the government's motion for summary judgment and, to the

extent that plaintiffs' case depends upon expert witness testimony, the plaintiffs' failure to produce expert testimony supporting their case requires that the government's motion be granted.

The second issue raised by plaintiffs' response is whether plaintiffs' claim constitutes a medical battery that can proceed without expert testimony. Plaintiffs argue that it does, and they cite the case of Blanchard v. Kellum, 975 S.W.2d 522 (Tenn. 1998). In a typical medical case alleging lack of informed consent, Tennessee statutory law requires expert testimony to prove that the information provided by a practitioner to the patient did not comply with the standard of care in the community. See Tenn. Code Ann. § 29-26-115. However, the Tennessee Supreme Court has distinguished a medical battery from a typical informed consent case. The Blanchard court stated as follows:

> We believe that there is a distinction between: (1) cases in which a doctor performed an unauthorized procedure; and (2) cases in which the procedure is authorized but the patient claims that the doctor failed to inform the patient of any or all the risks inherent in the procedure. Performance of an unauthorized procedure constitutes a medical battery. A simple inquiry can be used to determine whether a case constitutes a medical battery: (1) was the patient aware that the doctor was going to perform the procedure (i.e., did

> the patient know that the dentist was going to perform a root canal on a specified tooth or that the doctor was going to perform surgery on the specified knee?); and, if so (2) did the patient authorize the performance of the procedure? A plaintiff's cause of action may be classified as a medical battery only when answers to either of the above questions are in the negative. If, however, the answers to the above questions are affirmative and if the plaintiff is alleging that the doctor failed to inform of any of the risks or aspects associated with a procedure, the patient's cause of action rests on an informed consent theory.

975 S.W.2d at 524.

From a review of the complaint, it appears that plaintiffs concede that Mrs. Halliman knew that she was to have a colonoscopy on December 10, 1999, and that she consented to it. In the "Background" paragraph of her complaint, Mrs. Halliman states in part: "although my (sic) I really did not want the procedure, my husband convinced me to agree to the colonoscopy." Elsewhere in the complaint Mrs. Halliman states as follows:

> It must be kept in mind that I am Korean and do not read English. While I understand basic spoken English, I have difficulty comprehending expla-

> nations that are complex. The consent form was signed on December 6, 1999. My husband was not present at that time because he was working in Louisiana. It is highly that I signed the consent form without fully comprehending what the risks were. Because I am obsessive compulsive and would have had a tremendous fear of the procedure had I known the risk, I would not have consented to the procedure had I fully comprehended what the risk was.

From this allegation it is clear that plaintiffs' claim is not a medical batter as defined by Blanchard, but instead is an informed consent claim that requires expert testimony pursuant to Tennessee Code Annotated § 29-26-118.

In summary, plaintiffs' claims of medical malpractice and of lack of informed consent both must be proved by expert testimony under Tennessee law. In the absence of expert testimony to support plaintiffs' claims, there can be "no genuine issue as to any material fact," since a complete failure of proof concerning an essential element of the plaintiffs' case renders all other facts immaterial. Celotex, 477 U.S. at 323. Summary judgment for defendant is therefore appropriate.

RECOMMENDATION

For the reasons stated above, the undersigned RECOMMENDS that the government's mo-

tion for summary judgment be GRANTED and the complaint DISMISSED.

Under Rule 72(b) of the Federal Rules of Civil Procedure, any party has ten (10) days from receipt of this Report and Recommendation in which to file any written objections to this Recommendation, with the District Court. Any party opposing said objections shall have ten (10) days from receipt of any objections filed in this Report in which to file any response to said objections. Failure to file specific objections within ten (10) days of receipt of this Report and Recommendation can constitute a waiver of further appeal of this Recommendation. Thomas v. Arn, 474 U.S. 140 (1985), reh'g denied. 474 U.S. 1111 (1986).

ENTERED this 15th day of February, 2007.

s/ John S. Bryant
JOHN S. BRYANT
United States Magistrate Judge

APPENDIX D

Tennessee Code Annotated

§ 29-26-115. Claimant's burden in malpractice action – Expert testimony – Presumption of negligence – Jury instructions

(a) In a malpractice action, the claimant shall have the burden of proving by evidence as provided by subsection (b):

1. The recognized standard of acceptable professional practice in the profession and the specialty thereof, if any, that the defendant practices in the community in which the defendant practices or in a similar community at the time the alleged injury or wrongful action occurred;

2. That the defendant acted with less than or failed to act with ordinary and reasonable care in accordance with such standard; and

3. As a proximate result of the defendant's negligent act or omission, the plaintiff suffered injuries which would not otherwise have occurred.

(b) No person in a health care profession requiring licensure under the laws of this state shall be competent to testify in any court of law to establish the facts required to be established by

subsection (a),unless the person was licensed to practice in the state or a contiguous bordering state a profession or specialty which would make the person's expert testimony relevant to the issues in the case and had practiced this profession or specialty in (1) of these states during the year preceding the date that the alleged injury or wrongful act occurred. This rule shall apply to expert witnesses testifying for the defendant as rebuttal witnesses. The court may waive this subsection (b) when it determines that the appropriate witnesses otherwise would not be available.

(c) In a malpractice action as described in subsection (a), there shall be no presumption of negligence on the part of the defendant; provided, there shall be a rebuttable presumption that the defendant was negligent where it is shown by the proof that the instrumentality causing injury was in the defendant's (or defendants') exclusive control and that the accident or injury was one which ordinarily doesn't occur in the absence of negligence.

(d) In a malpractice action as described in subsection (a), the jury shall be instructed that the claimant has the burden of proving, by a preponderance of the evidence, the negligence of the defendant. The jury shall be further instructed that injury alone does not raise a presumption of the defendant's negligence.

§ 29-26-118 Proving inadequacy of consent. –

In a malpractice action, the plaintiff shall prove by evidence as required by § 29-26-115(b) that the defendant did not supply appropriate information to the patient in obtaining informed consent (to the procedure out of which plaintiff's claim allegedly arose) in accordance with the recognized standard of acceptable professional practice in the profession and in the specialty, if any, that the defendant practices in the community in which the defendant practices and in similar communities

APPENDIX E

Informed Consent in Clinical Medicine*

Peter B. Terry, MD, MA, FCCP

Over the past third of a century, there has been a revolution in the way that health-care providers and patients make most medical decisions. Paternalism has slowly gone the way of the long-play record, and in its place has emerged a consent process in which the patient is a more fully

informed and active participant. This process takes time however, and for the busy health-care provider there is often the temptation to hand the patient a consent form to sign. It is important to realize that signing a consent form does not constitute informed consent. True informed

consent is a process, and, as such, it requires that the health-care provider enter into a discussion that ultimately leads to the patient understanding of their options, and the risks and benefits of the alternative courses of action. The purpose of this article was to describe, in some detail, the consent process in practical clinical terms, and to note when and how it should be obtained.

Just as medicine has evolved over the past 200 years into a sophisticated profession that can often alleviate symptoms and cure disease, so also has the physician-patient relationship evolved from one of paternalism to one of a more equal partnership in the United States.1 A cornerstone of this new relationship is the belief that respect for patients and

their values is right and essential to good medical care. From this flows the obligation to obtain a patient's informed consent when decisions must be made about significant diagnostic and therapeutic interventions. But what is informed consent? The concept of informed consent has been evolving over the past 100 years based largely on case law early in the last century and later influenced by the Nuremberg trials, influential articles such as those of Henry Beecher, and contemporary bioethical thought beginning in the 1960s in the United States.2–5 Informed consent in medical research will be discussed in a subsequent article in this series.

Informed consent may be defined as the autonomous act by a patient or research subject to expressly permit a professional person to perform a medical action on the patient or to include a person in a research project.2 Although much has been written about each element of this definition (eg, autonomous act, expressly permitted), and its philosophical underpinnings, it seems most important for the busy physician to understand the practical implications of this definition. Below are cases that exemplify important aspects of informed consent.

Elements of Informed Consent

Case 1

A pulmonologist, seeing a patient in the outpatient clinic for a new asymptomatic infiltrate, recommends bronchoscopy. She hands the patient a detailed consent form that describes the risks, benefits, and alternatives to bronchoscopy, and asks

him to take his time reading it. Coming back a few minutes later, the pulmonologist asks the patient if he has any questions. The patient has none and signs the consent form, which is witnessed by a nurse.

•

Has the physician obtained informed consent? Yes and no.

Yes, from the legal and administrative perspective of a hospital the physician has obtained consent. Indeed, some hospitals have a patient sign a generic "consent-to-treat" form on admission. However, a signed consent form does not prevent a lawyer from pursuing a malpractice suit nor does it ensure a legal judgment in favor of the physician.

No, from the perspective of obtaining an ethically valid form of consent, the patient has not given consent. Informed consent is not a signed piece of paper; it is a process.2 What is written on a consent form is only a part of the process. A consent form gives information, but it does not give understanding, an obligation that a physician obtaining consent needs to ensure.

Obtaining true informed consent consists of a number of critical elements.2 These include the following: (1) disclosure of the pertinent medical facts and alternative courses of action; (2) ensuring patient capacity to understand the decision to be made; (3) ensuring patient understanding of the medical information; (4) the absence of coercion or manipulation; and (5) the

ability to consent. There are no national standards enumerating which procedures or decisions require informed consent by the patient in the United States.6 Indeed,

in one study6 marked variability within and between hospitals was found in obtaining informed consent for procedures among ICUs and internal medicine programs. At present, hospitals and their medical

staffs are left to develop local guidelines for obtaining consent. Although there is no formally recognized threshold of risk above which we ought to obtain informed consent, one ethical guideline might be any risk that is of a greater magnitude than that which we might ordinarily encounter when carrying out normal daily activities. Future guidelines for when to obtain informed consent in gray areas may be developed by determining societal expectations. Some hospitals have attempted to amalgamate the consent process into a single blanket consent signed early in the hospital course.6 This may be administratively acceptable but is not ethically acceptable unless the patient waives their right to make decisions.

Disclosure: When are physicians obligated to disclose information about a treatment or test? When a physician performs a venipuncture to obtain a blood sample from an adult patient, the physician does not feel obligated to obtain written or verbal consent. Because the risks are small, and because most adults have already had a venipuncture, they know what to expect. However, when a thoracic

surgeon sits down with a patient about to undergo lung transplantation, the surgeon feels obligated to carefully discuss all of the risks, benefits, and alternatives to having surgery. These two scenarios represent ends of the spectrum of the concept of proportionality with respect to disclosure. The notion of proportionality suggests that the greater the risk we are asking the patient to expose themselves to, the greater our obligation to disclose the risks, benefits, and alternatives to the procedure.

What has to be disclosed to the patient? Clearly, the physician must disclose enough information so that the patient can make an informed decision. What that entails has been evolving over the last 100 years.2 At the beginning of the 20th century, the standard (whatever the physician felt should be disclosed). With the influence of case law and contemporary bioethics, the standard has become one in which the physician must disclose the information that a reasonable person would want to know before making a decision. This so-called prudent-person standard applies to information about the harms, benefits, and alternative treatment strategies. The concepts of likelihood and magnitude of harm also assist the physician in deciding what risks to disclose when talking about diagnostic and therapeutic decisions. A reasonable guideline is to describe the complications/side effects that have a high likelihood of occurring even if they are minor in nature (eg, nausea or transient fever), and to describe the complications/side effects that have a low but not rare likelihood of occurring but are of such a magnitude of harm that they would give the pru-

dent person pause when making decisions (eg, 5 to 10% chance of dying). Complications and side effects that have a moderate chance of occurring and are mild or moderate in their severity should be disclosed, dependent on the circumstances. When obtaining consent and after giving the patient information that a reasonable person would want to know, it is vital to ask the patient whether there is any other information needed to make a decision. This allows the patient to ask questions, and thus sets an even higher standard, a subjective standard of disclosure. By asking whether there is anything else the patient wishes to know, this allows the patient to ask questions that reflect their unique sense of values and concerns. For example, some patients are more risk averse than others, and want to know more about the likelihood and consequences of complications or side effects than the physician would discuss with the average patient.

Capacity and Competence: Capacity is a medical concept and Implies that a patient has the ability to understand and weigh medical information and make decisions. Capacity may fluctuate (eg, whenthe patient goes in and out of a delirium). Most patients have the ability to understand simple choices, but **as the risks and benefits of choices increase in magnitude and complexity some with limited capacity or less formal education may be unable to give true informed consent.** Again

the concept of proportionality applies here. As the complexity of a decision and the magnitude of the consequences increase, so does the physician's obligation to ensure that the patient has the capacity to make the decision. Asking the patient to describe the treatment or test and its risks, benefits, and alternatives will often allow the physician to determine whether the patient has the capacity to understand and weigh the choices at hand. If there is a concern, asking the patient questions that test mental status is appropriate.7 More formal cognitive testing and a psychiatric consultation may be appropriate in some instances. **Even when the patient has the capacity to make a decision, the patient may not understand the words or concepts presented by the physician**. For example, a 10% chance of a complication may need to be translated into "for every 100 people who have this procedure, 90 of them will not have the complication, but 10 will." It is important to understand that capacity and competence mean different things. Competence is a legal term. Society and the law presume all persons to be competent until legally judged otherwise. A judicial declaration of incompetence is a legal declaration that the patient can no longer manage his or her affairs. This declaration may only be made or rescinded by a judge. Guardianship generally follows when a person is declared to be legally incompetent. Physicians and families routinely make decisions for patients who have been judged to be incapacitated without subjecting the patient to a formal competence hearing. This is justifiable if the patient has been judged by the physician to be

incapable of understanding the nature of the decision, its alternatives, and the accompanying risks, benefits, and consequences.

A less commonly recognized problem related to capacity is that of acceptance. A patient may understand all of the factual information that the physician gives him or her, but may not believe that some of it is true. For example, a patient in the ICU may have a life-threatening illness, be told about it, and be able to comprehend the risks and the benefits of the treatment options, but makes a decision that he or she would not otherwise make because the patient does not accept the life-threatening nature of the illness. When it is determined that a patient does not have the capacity to make the medical decision at hand, a surrogate (ie, a substitute decision maker) should make the decision. Ideally, all persons would have named a surrogate via an advance directive. In fact, most patients have not, so that we traditionally turn to the immediate family to act in the patient's best interest. Studies have shown that the person the patient would want to make decisions for him/her (ie, the moral surrogate) is usually the same person that state law would name as the decision maker (legal surrogate).8 Occasionally, the legal surrogate does not act in the patient's best interest (ie, is not also the moral surrogate). In such instances, the physician must ensure, if necessary through an ethics committee and/or court proceedings, that someone who will act in the patient's best interest is named.

Physicians may be asked to offer guidance to the surrogate in terms of how decisions should be made. The first suggestion is that the surrogate try to make a decision based on prior discussions with the patient (known as substituted judgment). In the absence of such discussions, the physician should suggest that the surrogate make the decision based on his or her best sense of the values and beliefs of the patient (knows as best interest judgment). If the surrogate has had little contact with the patient and does not know the values and beliefs of the patient, then the surrogate should be advised to make a decision that a prudent person would make in the circumstances. In the absence of detailed discussions with patients about their preferences for various treatments, there is a reasonable likelihood that the family (ie, surrogates) cannot accurately predict what decision the patient would make.8–10 Is this a persuasive argument against family members (surrogates) making decisions for patients? Most who have thought about this argue that this is not a compelling reason to dismiss family decision making as being invalid. In one study,11 when patients were asked whose preferences should prevail when there was a conflict between the patient's advance directive and the family's wishes, more than half the patients said that their advance directive should be ignored and the family's wishes followed.

Physician Decision-Making Influence: There are three ways that a physician can influence a

patient's decision making. These are rational persuasion, coercion, and manipulation.5 Rational persuasion implies that the patient makes the decision based on the logic of the factual information the physician has given coupled with the patient's own values. Ideally, physicians should use only this method of influencing patient decision making. Coercion implies that the patient is threatened in some way, such that a decision is made that the patient may not

Case 2

A physician believes that the best decision that a patient can make related to an impending elective surgical procedure is to refuse it. The physician also knows that the patient is very risk averse. So the physician, during the process of obtaining informed consent, tells the patient (while raising her eyebrows) that he has a 5% chance of dying as a result of a complication of the surgery. The physician could have given the patient the same information by saying that the patient had a 95% chance a having a successful surgery but chose to emphasize the risks in order to influence the patient to make the decision the way that the physician wanted it to be made. This more pervasive and subtle but inappropriate form of presenting information is called manipulation. Manipulation implies that the physician gives information to the patient either selectively or through emphasizing or deemphasizing some information inappropriately so as to make attractive to the patient the decision that the physician thinks is best for the

patient. A common form of manipulation is called framing. Consciously or unconsciously, physicians will often frame information, emphasizing or minimizing the risks or benefits of one of the choices so that the patient makes the decision that the physician wants them to make. The patient does not know that as we are presenting the choices to them in a seemingly objective manner, we are actually conflating the factual information of decision making with our own opinion about what is the best decision. It is better to state the facts objectively and then separately give the patient your opinion about the best course of action.

Ability to Consent: Rare instances may occur in which a patient fulfills all of the other criteria for informed consent but cannot give consent. For example, a patient may be in a "locked-in" state and may literally be unable to convey the decision to the health-care providers, even though they may have made an informed decision.

Who Should Give Informed Consent

Case 3

The condition of an 81-year-old retired janitor, who was not previously your patient but is now under your care, is deteriorating in the ICU. A decision must be made about resuscitation. The patient is alert, cooperative, and, in your judgment, appears to have the capacity to make any necessary decisions. You discuss the treatment options, risks, and benefits with the patient, and, after much dis-

cussion, you ask him what he would prefer that you do. Is this the right question to ask? No, because this question presumes that he wants to make the decision. Additionally, the patient may have assumed that he must make the decision because you asked. It is widely recognized that patients have the right to make decisions for themselves. But many mistakenly believe that because this right exists, patients must and will always choose to exercise it. There is a growing body of empirical evidence suggesting that in a variety of circumstances patients would prefer not to make decisions by themselves. Rather, they often want to share decision making with family and/or their physician or want others to make decisions on their behalf. These observations suggest that, when obtaining informed consent, we ask first who and how they want to make decisions, rather than what decision they want to make.

Cultural Diversity and Informed Consent

Sensitivity to cultural values must always be an important consideration when obtaining informed consent, and the United States, which is a country of immigrants, is increasingly a multicultural society. Importantly, many cultures place family values above those of the individual and do not value the individual decision making that has become common practice in the past half century. For example, it is considered an insult in some Arabic cultures if the physician asks the patient to sign a consent document.

It is essential to understand the culture of a pa-

tient and, if necessary, meet the patient privately, perhaps with the help of an interpreter, to determine what information the patient wishes to know and how the patient wishes the consent process to proceed. Do not use family as interpreters because they may not accurately express the patient's wishes. If patients choose to allow their spouses, family, or elders to make decisions on their behalf, then they have expressed their autonomous wish to allow others to make these decisions.

When Consent Is Unnecessary

Case 4

A young woman in your ICU is in shock secondary to massive pulmonary emboli. Because of the small, isolated nature of the hospital, there are no surgical or transport options available. You have the capacity to give the patient a thrombolytic agent but wish to

obtain informed consent from her next-of-kin because of the significant risks associated with its use. After many frantic attempts to contact a family member, none is found. Should you give her the

agent without obtaining consent? It is not necessary to obtain informed consent in emergency circumstances if delay will increase the risk of significant harm and there is a reasonable likelihood that the patient will benefit from the treatment. The challenge is in defining what we mean by the terms significant harm and benefit. The meaning of harm and benefit must be determined by the physician in the clinical context. In the case cited in previous sections, most would agree that death is a likely

significant harm without treatment. Most physicians would agree that there is significant chance of benefit from the use of the thrombolytic agent. But there may be disagreement as to whether the likelihood of an intracranial bleed secondary to therapy constitutes a significant risk.

Another circumstance in which it is not necessary to obtain informed consent occurs when a patient waives the right to go through the informed consent process. Some patients trust their physician or family implicitly, do not wish to know certain information related to decision making, and may waive their right to give consent. This is ethically and legally acceptable, but may be psychologically burdensome to the family/physician and has the potential to expose the patient to abuse.[5,17] Alternatively, some patients wish to know and understand the choices before them, but choose to let the physician make decisions on their behalf.

A rarely invoked reason not to obtain informed consent is what is known as the therapeutic privilege. Some states legally allow a physician to withhold information needed by the patient to give informed consent if there is a reasonable likelihood that the patient would be harmed by hearing the information. An example might be the withholding of information from a severely depressed patient who has attempted suicide in the past when given similar information. This does not mean that the patient should never be given important information in such circumstance; rather, if they are told, the

in such circumstance; rather, if they are told, the physician must make preparations in advance to reduce the patient's risk of self-harm by involving psychiatry and the patient's family in the disclosure process.

Assent

A 16-year-old person may have the capacity to give ethical consent (called assent) but cannot sign the hospital consent form because of age restrictions on the definition of an adult. At progressively younger ages, the ability of a child to reason becomes questionable,

but it remains incumbent on the physician to help minors understand, as much as possible, the decision that must made by their parents and to obtain their assent to the decision.

Conclusion

Informed consent is a cornerstone of patient-physician interactions. Even the most mundane of patient-physician interactions, that of writing a prescription, is an opportunity to practice I formed

consent and may even enhance patient adherence. It can be time consuming and frustrating, especially when the patient makes a choice with which the physician does not agree. But as physicians we must be cautious not to inject our own sense of values into decision making unless it is clear to the

patient what part of the discussion is factual and what part reflects our values and opinion. We must continually remind ourselves that it is our responsibility to give the patient the information they need to make a decision and to ensure that they understand it. Informed consent exists to allow the patient to pursue their life plan by safeguarding their values and facilitating a rational decision-making process.